

### **REMARKS**

The Final Office Action mailed October 21, 2002, has been received and reviewed, and Applicants note with appreciation the Examiner's withdrawal of the previous claim rejection under 35 U.S.C. § 112. Claims 1 and 3 through 48 are rejected in the Office Action as being anticipated by the references cited therein. Applicants respectfully note that claims 1, 3 through 16, 28, 32, and 42 through 48 are canceled herein without prejudice or disclaimer, and claims 17 through 27, 29 through 31, and 33 through 41 are amended herein. Moreover, Applicants have herein added new claims 49 through 53, and Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

### **35 U.S.C. § 102 Rejections**

Claims 1, 3 through 7, 15, 22, 23, 27 through 29, 36, and 42 through 45 stand finally rejected under Section 102(b) as being anticipated by one of Clark et al. (U.S. 5,374,620) and Sparks et al. (U.S. 4,952,402). However, because claims 1, 3 through 7, 15, 28, and 42 through 45 are cancelled herein, Applicants address this rejection only as it could be applied to claims 22, 23, 27, 29, and 36.

In order for a reference to anticipate a claim under Section 102(b), that references must expressly or inherently set forth each and every element recited in the claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In this instance, Applicants respectfully submit that neither of the references cited in the Office Action teaches or shows the subject matter recited in any of claims 22, 23, 27, 29, and 36 in as complete detail as is provided in the claims. Therefore, Applicants respectfully traverse the rejection of claims 1, 3-27, and 29-48 under Section 102(b) and request that such rejection be withdrawn.

Claims 22, 23, 27, and 29 are directed to formulations that include at least one beneficial agent and a non-aqueous single phase biocompatible vehicle. The vehicle included in the formulations recited in claims 22, 23, 27 and 29 comprises solvent, surfactant, and polymer, wherein the

solvent is a lauryl alcohol and the solvent, surfactant, and polymer are selected and formulated such that the vehicle exhibits a viscosity capable of suspending the beneficial agent. However, Applicants respectfully submit that Clark et al. and Sparks et al. fail to expressly or inherently teach a formulation including a vehicle as defined in any of claims 22, 23, 27 and 29. Therefore, Applicants respectfully submit that Clark et al. and Sparks et al. do not anticipate claims 22, 23, 27 and 29, and Applicants respectfully request that the rejection of these claims under Section 102 be withdrawn.

Claim 36 is directed to a method for treating a subject suffering from a condition that may be alleviated by administration of a beneficial agent. The method of claim 36 includes administering to the subject a therapeutically effective amount of a formulation that includes at least one beneficial agent and a non-aqueous single phase biocompatible vehicle. The vehicle included in the formulation administered in the method of claim 36 comprises solvent, surfactant, and polymer, wherein the solvent is a lauryl alcohol and the solvent, surfactant, and polymer are selected and formulated such that the vehicle exhibits a viscosity capable of suspending the beneficial agent. However, neither Clark et al. nor Sparks et al. expressly or inherently teaches a formulation that includes a vehicle as defined in claim 36. Consequently, Applicants respectfully submit that neither reference anticipates claim 36, and Applicants respectfully request that the rejection of claim 36 under Section 102 be withdrawn.

It is asserted in the Office Action that even though the “the prior art does not specifically state viscous and single-phase and non-aqueous, a composition or formulation that comprises a surfactant and a polymer or surfactant and solvent or solvent and polymer would inherently have the properties claimed.” *See, Office Action*, page 3. Similarly, it is also asserted in the Office Action that “the composition of the prior art is inherently viscous and single phase because the prior art teaches a composition comprising a solvent, surfactant and polymer.” *See, Office Action*, page 4. If it is the Examiner’s assertion that the teachings of Clark et al. and Sparks et al. inherently anticipate the claims pending in the present application, then it is the Examiner’s burden to provide evidence “that must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by

persons of ordinary skill in the art.” *See, M.P.E.P.*, § 2112, p. 2100-51. In other words, “[i]n relying on the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See, M.P.E.P.*, § 2112, p. 2100-52, *emphasis in original*. Significantly, “[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *See, Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). Therefore, in order for the Examiner to properly establish that either Clark et al. or Sparks et al. inherently anticipates the rejected claims, the Examiner bears the burden of providing a basis in fact and/or technical reasoning that establishes that each time formulations as taught in Clark et al. or Sparks et al. are prepared, a vehicle or formulation as recited in the rejected claims necessarily results. Applicants respectfully submit that such a burden has not been met.

Applicants respectfully note that the Office Action provides no basis in fact or technical reasoning that reasonably supports a determination that the subject matter recited in the rejected claims necessarily flows from the teachings of either Clark et al. or Sparks et al. In particular the Office Action includes no evidence to support the assertion that every composition or formulation that comprises solvent, surfactant and would necessarily result in a non-aqueous, single-phase, and biocompatible vehicle that exhibits a viscosity capable of suspending the beneficial agent. Applicants respectfully submit that every composition or formulation that includes a combination of solvent, surfactant, and polymer will not necessarily provide a material that is non-aqueous, single-phase, biocompatible, and exhibits a viscosity suitable to suspend a beneficial agent. Therefore, Applicants respectfully submit that if it is to be argued that either Clark et al. or Sparks et al. inherently teaches a vehicle or formulation as recited in the rejected claims, the burden of establishing a reasonable basis for a finding of inherency remains with the Examiner.

### **Double Patenting**

The Examiner has provisionally rejected claims 1, and 3 through 48 under 35 U.S.C. 101 as claiming the same invention as claims 1-42 of co-pending Application No. 09/497,422. Applicants note that claims 1, 3 through 16, 28, 32, and 42 through 45 are cancelled herein and that such a provisional rejection should be withdrawn from these cancelled claims. Applicants further note that, as it relates to any claims presently pending in the application, the double patenting rejection included in the Office Action is a provisional rejection.

### **CONCLUSION**

Claims 17 through 27, 29 through 31, 33 through 41, and 49 through 53 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

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Respectfully submitted,

  
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